REMARKS

Claims 1-34 and 37-38 are pending in this application. Claims 35-36 have been canceled. Claims 5, 9, 10, 11, 12, 28, 29, 30, 31, and 38 have been amended. These amendments address informalities in the originally presented claims, and no new matter has been added.

The applicant thanks the examiner for the in-person interview on June 14, 2007 and the productive discussion that ensued. As discussed at that time, the applicant believes that there are significant differences between the endoscopic imaging system of U.S. Pat. No. 6,293,911 to Imaizumi and Dr. Frangioni's open surgical imaging system. While certain claims in the pending application relate to subject matter that might be incorporated into an endoscopic system, there appears to be no motivation in Imaizumi or the balance of the endoscopic imaging art and other prior art of record to suggest Dr. Frangioni's inventive imaging techniques.

It is noted that the applicant was aware of Imaizumi at the time the present application was filed, and the applicant's claims are drawn specifically to features that are believed to be entirely absent from Imaizumi. It is further noted for the record that due to the variations in scope for each of the independent claims pending in this application, no argument or comment with respect to any one of the independent claims should be construed as applying to any other one of the independent claims absent an explicit indication to the contrary.

Claim Objections

The applicant has revised claim 5 as suggested by the examiner. The applicant has also addressed an inconsistency in the dependent claims by amending the multiple dependent claims that refer to a sequential list of claims so that they consistently use the term "through" to specify a sequential list rather than a dash or hyphen. The applicant thanks the examiner for identifying these informalities.

The examiner has also objected to claim 32 as lacking support for means-plus-function form. With respect to this claim, the applicant submits that the originally filed specification clearly identifies a structure for performing each of the recited functions, and that the applicant expressly intends to invoke 35 U.S.C. § 112, ¶ 6 with respect to this

claim. Example of structures corresponding to each recited function of claim 32 are provided below:

a visible light means for illuminating a subject with one or more wavelengths of visible light;

A structure that performs the function of illuminating a subject with one or more wavelengths of visible light is disclosed, for example, as the visible light source 102. "In general, the visible light source 102 and the excitation light source 104 illuminate the surgical field 106." Page 13, lines 8-9. "The visible light source 102 may be, for example, a near-infrared depleted white light source. This may be a one-hundred fifty Watt halogen lamp with one or more filters to deplete wavelengths greater than 700 nanometers ("nm")." Page 14, lines 13-15. Other far-red depleted white light ranges may also be appropriate depending upon the selection of a particular fluorescent substance for diagnostic imaging. For example, a white light source depleted at 650 nm and above may be usefully employed "with Cy5 dye, which emits light when excited at 650 nm." Page 14, lines17-19. As another useful example, Cy5.5 emits light efficiently when excited at wavelengths above 650 nm.

an excitation light means for illuminating the subject with an excitation wavelength that is not one of the one or more wavelengths of visible light;

A structure that performs the function of illuminating the subject with an excitation wavelength that is not one of the one or more wavelengths of visible light is disclosed, for example, as the excitation light source 104. "In general, the visible light source 102 and the excitation light source 104 illuminate the surgical field 106." Page 13, lines 8-9. "The excitation light source 104 provides light at a wavelength that excites the dye 110. This may be, for example, a laser diode such as a 771 nm, 250 mW laser diode system, which may be obtained from Laser Components of Santa Rosa, California. Other single wavelength, narrowband, or broadband light sources may be used, provided

they do not interfere with the visible light image captured by the video camera 122 or the emission wavelength of the dye 110." Page 15, line 19 – Page 16, line 1.

a fluorescence means introduced into a subject, the fluorescence means for dissolving in blood carried by the circulatory system and for emitting photons at an emission wavelength in response to the excitation wavelength;

Structures (the dyes or other fluorescent substances) that performs the function of dissolving in blood and emitting photons at an emission wavelength in response to the excitation wavelength are discussed at length at Page 17, line 9 – Page 33, line 21. Specific dyes such as IR-786 (p. 33, l. 6), IRDye78-CA (p. 32, l. 16), indocyanine green (p. 31, l. 10), fluorescein, and methylene blue (p. 8, l. 10) are identified as specific examples of corresponding structures. As discussed during the interview of June 14, 2007, imaging of the *circulatory system* as claimed in claim 32 employs dyes in small molecule form that dissolve easily in blood, a feature that is not present in the dyes disclosed in the endoscopic prior art of record which generally include moieties for preferential uptake at a region of interest.

an imaging means for capturing a visible light image of the subject and an emission wavelength image of the circulatory system of the subject; and

A structure that performs the function of capturing a visible light image and an emission wavelength image of the circulatory system is described for example as the video camera 122 and the near-infrared camera 120 at Page 13, lines 10-14 ("An image from the surgical field 106 is then captured by two cameras, the video camera 122 capturing a conventional, visible light image of the surgical field 106 and the near-infrared camera 120 capturing a diagnostic image based upon the distribution of the dye 110 in the surgical field 106."). The near-infrared camera 120 is described in greater detail, for example, at Page 35, lines 6-10 ("The near-infrared camera 120 may be any

still or moving image camera suitable for capturing images at the emission wavelength of the excited dye 110. The near-infrared camera may be, for example, an Orca-ER near-infrared camera with settings of gain 7, 2 x 2 binning, 640 x 480 pixel field of view, and an exposure time of 20 msec and an effective frame rate of fifteen frames per second."). The video camera 122 is described in greater detail, for example, at Page 35, lines 19-23 ("The video camera 122 may be any video camera suitable for capturing images of the surgical field 106 in the visible light spectrum. In one embodiment, the video camera 122 is a color video camera model HV-D27, commercially available from Hitachi of Tarrytown, New York.").

a display means for concurrently rendering the visible light image of the subject and the emission wavelength image of the circulatory system.

A structure that concurrently renders the visible light image of the subject and the emission wavelength image of the circulatory system includes the display 126 and image processing unit 124. ("[The visible light and emission wavelength] images may be combined by the image processing unit 124 and presented on a display 126 where they may be used, for example, by a surgeon conducting a surgical procedure.", Page 13, lines 14-16). The display 126 and image processing unit 124 are described in greater detail at, for example, Page 36, line 5 – Page 37, line 3.

Because the originally filed specification discloses structure for performing each of the functions recited in claim 32, the applicant respectfully requests that the examiner withdraw this objection and treat claim 32 as a means-plus-function claim under 35 U.S.C. § 112, ¶ 6 for purposes of examination.

Claim Rejections – 35 U.S.C. § 102

The examiner has rejected independent claims 1, 2, 3, 4, 32, 33, 34 and 37 under 35 U.S.C. § 102 as anticipated by U.S. Pat. No. 6,293,911 to Imaizumi et al. ("Imaizumi").

The pending claims are in general directed to multi-modal imaging systems that provide combined diagnostic and visible light images of a surgical site. While numerous prior art patents (such as Imaizumi) have been identified that apply multi-modal imaging in the context of endoscopic devices, the pending claims have been drawn specifically to features that are absent from the endoscopic prior art. As noted during the interview on June 14, 2007, these claims were more particularly drafted to expressly distinguish from Imaizumi, and each independent claim includes at least one feature that is believed to be entirely absent from Imaizumi. As explained in greater detail below, Imaizumi cannot by itself anticipate these claims.

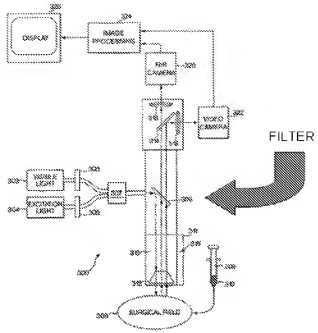
Independent Claim 1

The examiner has rejected independent claim 1 as anticipated by U.S. Pat. No. 6,293,911 to Imaizumi.

Claim 1 is directed to an imaging system having a shared optical path for a visible light source, an excitation light source, a reflected visible light image, and an emitted fluorescent image. This shared optical path is achieved through the use of a filter at a particular (and explicitly claimed) location in the imaging system and having particular (and explicitly claimed) optical properties. Specifically, the imaging system of claim 1 includes an "optical guide" connecting a lens to an imaging device, along with a filter for:

> coupling the visible light source and the excitation light source into the optical guide, the filter reflecting some of the light provided by the visible light source and some of the light from the excitation light source toward the subject, the filter further transmitting some visible light from the subject captured by the lens toward the electronic imaging device and the filter further transmitting the emission wavelength from the subject captured by the lens toward the electronic imaging device.

The location and operation of this filter may be readily understood with reference to Fig. 3 of the present application, where a filter 309 is depicted that embodies each of the elements recited in the filter of claim 1.



While Imaizumi discloses numerous uses of a dichroic mirror, filter, or the like, these filters generally serve in conventional roles such as separating fluorescence and visible light images at a camera head (like the dichroic mirror 314 in the figure above) or conditioning light sources for a particular imaging application. Nowhere does Imaizumi disclose a filter within an optical path that couples in visible light and excitation light on one hand, and transmits fluorescence and visible light on the other hand as presently claimed. Because Imaizumi does not disclose the claimed filter, or any other system for providing a single, shared optical path, Imaizumi cannot anticipate claim 1. The applicant respectfully requests that the examiner withdraw the rejection of claim 1 based upon Imaizumi.

Independent Claim 2

The examiner has rejected independent claim 2 as anticipated by U.S. Pat. No. 6,293,911 to Imaizumi.

Claim 2 is directed to an imaging system that captures diagnostic images of a circulatory system along with a visible light image. The diagnostic portion of this imaging modality is achieved, for example, by employing highly blood-soluble dyes in

small molecule form, a number of which are described in detail in the specification. As claimed, this fluorescent substance is "introduced into the circulatory system of the subject, the fluorescent substance being soluble in blood carried by the circulatory system and the fluorescent substance emitting photons at an emission wavelength in response to the excitation wavelength", and the resulting image is received by "an electronic imaging device that captures an image of a field of view that includes some portion of the subject and the circulatory system of the subject." This is readily distinguishable from the dyes of Imaizumi and the other visible light/fluorescent light endoscopic systems of the prior art which uniformly disclose dyes having ligands or other moieties selected for preferential uptake at a location of diagnostic significance. The dyes disclosed in the prior art tend to accumulate at specific locations, and accordingly interfere with circulatory system imaging that is the intended use of the system of claim 2. Because Imaizumi does not disclose a fluorescent substance that is soluble in blood or an electronic imaging device that captures an image of the circulatory system of a subject, Imaizumi cannot anticipate claim 2. The applicant respectfully requests that the examiner withdraw the rejection of claim 2 based on Imaizumi.

Independent Claim 3

The examiner has rejected independent claim 3 as anticipated by U.S. Pat. No. 6,293,911 to Imaizumi.

Claim 3 is directed to an imaging system used in "an operating area closed to ambient light, the operating area including a surgical field where a surgical procedure may be performed on a subject." As explained in the specification in some detail, this term is intended to expressly distinguish from endoscopic, laparascopic, or other effectively internal surgical imaging systems:

> The imaging system 100 may be surrounded by an operating area (not shown) closed to ambient light. As will become clear from the following, many visible light sources such as incandescent lamps, halogen lamps, or daylight may include a broad spectrum of electromagnetic radiation that extends beyond the range of visible light detected by the human eye and into wavelengths used in the present system as a separate optical channel for generating diagnostic images. In order to effectively detect emission in these super-visible light wavelengths, it is preferred to enclose the surgical field 106, light sources 102, 104, and cameras 120, 122 in an area

> that is not exposed to broadband light sources. This may be achieved by using an operating room closed to external light sources, or by using a hood or other enclosure or covering for the surgical field 106 that prevents invasion by unwanted spectrum. The visible light source 102 may then serve as a light source for the visible light camera 122, and also for provide conventional lighting within the visible light spectrum. As used herein, the term "operating area" is intended specifically to refer to an open surgical site that is closed to ambient light. Endoscopic or laparoscopic applications, as described below, are confined to surgical procedures within a closed body cavity, and do not include an operating area as that term is intended herein.

Page 13, line 18 – Page 14, line 11. Also as discussed at some length during the interview of June 14, 2007, the optics, lighting requirements, power requirements, and so forth differ significantly for an open surgical system compared to an endoscopic system. Some of these differences are noted in the specification (e.g., the use of a zoom lens with the claimed imaging system). As more generally explained by Dr. Frangioni during the interview, it is not possible to simply take the endoscope taught by Imaizumi out of the body and capture images – For a variety of reasons ranging from the fixed-focus optics of endoscopes to the interference of broadband ambient light with fixed-wavelength fluorescence images, an endoscopic (or laparascopic) system is not useful for capturing images in an open surgical system. Because Imaizumi does not teach an imaging system for use with an open operating area as presently claimed, Imaizumi cannot anticipate claim 3. The applicant respectfully requests that the examiner withdraw the rejection of claim 3 based on Imaizumi.

Independent claim 4

The examiner has rejected independent claim 4 as anticipated by U.S. Pat. No. 6,293,911 to Imaizumi.

Claim 4 is directed to an imaging system that captures diagnostic images of a circulatory system along with a visible light image as discussed above with reference to claim 2. The diagnostic portion of this imaging modality is achieved, for example, by employing highly blood-soluble dyes in small molecule form, a number of which are described in detail in the specification. As claimed, this fluorescent substance is "introduced into the circulatory system of the subject, the fluorescent substance being

soluble in blood carried by the circulatory system and the fluorescent substance emitting photons at an emission wavelength in response to the excitation wavelength", and the resulting image is received by "an electronic imaging device that captures an image of a field of view that includes some portion of the subject and the circulatory system of the subject." Because Imaizumi does not disclose a fluorescent substance that is soluble in blood or an electronic imaging device that captures an image of the circulatory system of a subject, Imaizumi cannot anticipate claim 2. The applicant respectfully requests that the examiner withdraw the rejection of claim 2 based on Imaizumi.

Claim 4 further distinguishes from the other endoscopic multimodal systems of the prior art by reciting the use of concurrent excitation and visible light illumination, or as recited in the claim: "an excitation light source that illuminates the subject *at the same time* that the visible light source illuminates the subject." As noted during the interview of June 14, 2007, this is a particularly useful feature for open surgical systems because it avoids the need for the power switching electronics and other hardware otherwise associated with the relatively large lighting systems required in an open environment (typically > 100 Watts, and typically switching at frequencies > 30 Hz for video rate imaging).

Independent Claim 32

The examiner has rejected independent claim 32 as anticipated by U.S. Pat. No. 6,293,911 to Imaizumi.

As with claim 2 above, claim 32 is directed to an imaging system that captures diagnostic images of a circulatory system along with a visible light image. The diagnostic portion of this imaging modality is achieved, for example, by employing highly blood-soluble dyes in small molecule form, a number of which are described in detail in the specification. As claimed the circulatory imaging system is achieved with "a fluorescence means introduced into a subject, the fluorescence means for dissolving in blood carried by the circulatory system and for emitting photons at an emission wavelength in response to the excitation wavelength," along with "an imaging means for capturing a visible light image of the subject and an emission wavelength image of the circulatory system of the subject." This is readily distinguishable from the dyes of

Imaizumi and the other visible light/fluorescent light endoscopic systems of the prior art which uniformly disclose dyes having ligands or other moieties selected for preferential uptake at a location of diagnostic significance. These dyes disclosed in the prior art tend to accumulate at specific locations, and accordingly interfere with circulatory system imaging that is the intended use of the system of claim 32. Because Imaizumi does not disclose a fluorescent substance that is soluble in blood or an electronic imaging device that captures an image of the circulatory system of a subject, Imaizumi cannot anticipate claim 32. The applicant respectfully requests that the examiner withdraw the rejection of claim 32 based on Imaizumi.

Independent Claim 33

The examiner has rejected independent claim 33 as anticipated by U.S. Pat. No. 6,293,911 to Imaizumi.

Claim 33 is directed to an imaging method that captures diagnostic images of a circulatory system along with a visible light image, as discussed above with reference to claim 2. For reasons similar to those provided for claim 2, claim 33 is believed to be patentable over Imaizumi. The diagnostic portion of the claimed imaging method is obtained, for example, by employing highly blood-soluble dyes in small molecule form, a number of which are described in detail in the specification. As claimed this method include "introducing a fluorescent substance into a circulatory system of the subject, the fluorescent substance being soluble in blood carried by the circulatory system and the fluorescent substance emitting photons at an emission wavelength in response to the excitation wavelength", along with "electronically capturing an emission wavelength image of the subject that shows the circulatory system." Because Imaizumi does not disclose a fluorescent substance that is soluble in blood or an electronic imaging device that captures an image of the circulatory system of a subject, Imaizumi cannot anticipate claim 2. The applicant respectfully requests that the examiner withdraw the rejection of claim 2 based on Imaizumi.

Claim 33 further distinguishes from the other endoscopic multimodal systems of the prior art by reciting the steps of "illuminating a subject with one or more wavelengths of visible light" and "concurrently illuminating the subject with an excitation wavelength

that is not one of the one or more wavelengths of visible light." As noted during the interview of June 14, 2007, this is a particularly useful feature for open surgical systems because it avoids the need to provide light switching hardware for the relatively large lighting systems required in an open environment (typically > 100 Watts, and typically switching at frequencies > 30 Hz for video rate imaging).

Independent Claim 34

The examiner has rejected independent claim 34 as anticipated by U.S. Pat. No. 6,293,911 to Imaizumi.

Claim 34 is directed to an imaging method including "enclosing a subject in an operating area closed to ambient light." As explained in the specification in some detail, the term "operating area" is intended to expressly distinguish from endoscopic, laparascopic, or other effectively internal surgical imaging systems:

> The imaging system 100 may be surrounded by an operating area (not shown) closed to ambient light. As will become clear from the following, many visible light sources such as incandescent lamps, halogen lamps, or daylight may include a broad spectrum of electromagnetic radiation that extends beyond the range of visible light detected by the human eye and into wavelengths used in the present system as a separate optical channel for generating diagnostic images. In order to effectively detect emission in these super-visible light wavelengths, it is preferred to enclose the surgical field 106, light sources 102, 104, and cameras 120, 122 in an area that is not exposed to broadband light sources. This may be achieved by using an operating room closed to external light sources, or by using a hood or other enclosure or covering for the surgical field 106 that prevents invasion by unwanted spectrum. The visible light source 102 may then serve as a light source for the visible light camera 122, and also for provide conventional lighting within the visible light spectrum. As used herein, the term "operating area" is intended specifically to refer to an open surgical site that is closed to ambient light. Endoscopic or laparoscopic applications, as described below, are confined to surgical procedures within a closed body cavity, and do not include an operating area as that term is intended herein.

Page 13, line 18 – Page 14, line 11. Also as discussed at some length during the interview of June 14, 2007, the optics, lighting requirements, power requirements, and so forth differ significantly for an open surgical system compared to an endoscopic system, some of which is also detailed in the specification. Because Imaizumi does not teach an

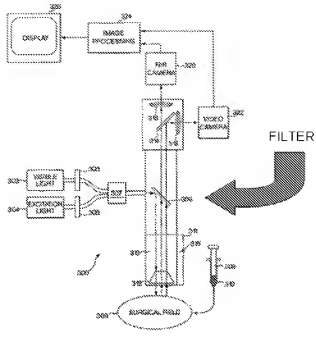
imaging system for use with an open surgical operating area as presently claimed, Imaizumi cannot anticipate claim 3. The applicant respectfully request that the examiner withdraw the rejection of claim 3 based on Imaizumi.

Claim 34 further distinguishes from the other endoscopic multimodal systems of the prior art by reciting the steps of "illuminating the subject with one or more wavelengths of visible light" and "concurrently illuminating the subject with an excitation wavelength that is not one of the one or more wavelengths of visible light." As noted during the interview of June 14, 2007, this is a particularly useful feature for open surgical systems because it avoids the need to provide light switching hardware for the relatively large lighting systems required in an open environment (typically > 100 Watts, and typically switching at frequencies > 30 Hz for video rate imaging).

Independent Claim 37

The examiner has rejected independent claim 37 as anticipated by U.S. Pat. No. 6,293,911 to Imaizumi.

Claim 37 is directed to an imaging method using a shared optical path for a visible light source, an excitation light source, a reflected visible light image, and an emitted fluorescent image. As claimed, this method includes the steps of "providing an endoscope having an optical path for directing images of the subject to an imaging device", "coupling the excitation wavelength and the one or more wavelengths of visible light into the optical path", and "capturing an emission wavelength image of the subject and a visible light image of the subject at the imaging device." In one embodiment, the shared optical path is achieved through the use of a filter described above. The location and operation of this filter may be readily understood with reference to Fig. 3 of the present application, where a filter 309 performs the coupling functions while permitting emission wavelength images and visible light images to pass to the imaging device.



While Imaizumi discloses numerous uses of a dichroic mirror, filter, or the like, these filters generally serve in conventional roles such as separating fluorescence and visible light images at a camera head (like the dichroic mirror 314 in the figure above) or conditioning light sources for a particular imaging application. Nowhere does Imaizumi disclose coupling visible light and excitation light sources into an optical path that *also* transmits reflected and fluoresced images to a camera as presently claimed. Because Imaizumi does not disclose the claimed method, or any other method for providing a single, shared optical path, Imaizumi cannot anticipate claim 1. The applicant respectfully requests that the examiner withdraw the rejection of claim 1 based upon Imaizumi.

Conclusion

The claims currently pending in this case, as amended above, are believed to be in condition for allowance.

The applicant requests that the examiner withdraw the outstanding rejections based upon Imaizumi and, if no other art is located that teaches the claimed combinations, that the examiner issue a notice of allowability for pending claims 1-34 and 37-38. If any questions arise concerning the foregoing, the examiner is encouraged to contact the undersigned.

Respectfully submitted
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